## SCHEDULE A

## **Definitions**

- The Procter & Gamble Company incorporates by reference herein the definitions Α. set forth in its First Set of Requests for the Production of Documents and Things.
- $\mathbf{B}$ . Teva U.S.A. means Teva Pharmaceuticals USA, Inc. and any and all officers, directors, employees, agents, attorneys, representatives, partners, affiliates and all other persons or entities acting or purporting to act or that have acted or purported to act on behalf of any of the foregoing.
- Teva Israel means Teva Pharmaceutical Industries, Ltd. and any and all officers, C. directors, employees, agents, attorneys, representatives, partners, affiliates and all other persons or entities acting or purporting to act or that have acted or purported to act on behalf of any of the foregoing.

## **Topics of Examination**

- The composition of Teva's ANDA Risedronate Sodium Tablets. 1.
- The synthesis of the risedronate sodium used in Teva's ANDA Risedronate Sodium Tablets 2. and Related Drugs.
- The decision by Teva U.S.A. and/or Teva Israel to develop a generic version of Actonel®. 3.
- Any studies, test, analyses, investigations and/or evaluations done by or on behalf of or 4. known to Teva U.S.A. and/or Teva Israel concerning the market for risedronate, the needs met by Actonel®, and the commercial success of Actonel®.
- The research, design, development and production of Teva's ANDA Risedronate Sodium 5. Tablets and Related Drugs, including without limitations any research and development relating to risedronate, any research and development relating to Actonel®, any research and development relating to generic versions of Actonel®, any research and development relating to alternatives to Actonel®, and the amount of money and time invested by Teva U.S.A. and/or Teva Israel in the research, design, and development of Teva's ANDA Risedronate Sodium Tablets.
- Any studies, test, analyses, investigations and/or evaluations done by or on behalf of or 6. known to Teva U.S.A. and/or Teva Israel concerning the bioavailability, absorption, toxicity, or metabolism of risedronate in mammals.
- The preparation and filing of ANDA 77-132, including without limitation, all tests, analyses, studies, information, evaluations, and data contained or referenced in ANDA 77-132, and/or relied upon by Teva U.S.A. and/or Teva Israel in preparing ANDA 77-132, the decision to prepare and file ANDA 77-132, and the amount of money and time invested by Teva U.S.A. and/or Teva Israel in the preparation and filing of ANDA 77-132.

- 8. The benefits, including revenues and profits, that Teva U.S.A. and/or Teva Israel projects or plans to obtain should ANDA 77-132 obtain approval from the U.S. Food and Drug Administration.
- 9. Knowledge, notice, and/or consideration by Teva U.S.A. and/or Teva Israel of the '122 patent prior to the filing of ANDA 77-132, including without limitation, the person(s) at Teva U.S.A. and/or Teva Israel who first learned of the '122 patent, the circumstances through which they first learned of the '122 patent, and any analysis of the '122 patent.
- 10. Any patent policy in effect at Teva U.S.A. and/or Teva Israel at any time since entry into the generic market for risedronate was first contemplated.
- 11. The factual basis for Teva's contention that Teva's ANDA Risedronate Sodium Tablets do not and will not infringe any claim of the '122 patent either directly or indirectly, or under the doctrine of equivalents.
- 12. The factual basis for Teva's contention that one or more claims of the patents-in-suit are invalid and unenforceable under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and more particularly under 35 U.S.C. §§ 102 and 103.
- 13. All prior art that Teva contends anticipates any claim of the '122 patent, including without limitation, the claim(s) of the '122 patent allegedly anticipated by each reference, the element(s) of each such claim allegedly described explicitly in the reference, and the element(s) of each such claim alleged to be inherent in the reference.
- 14. All prior art that Teva contends renders the '122 patent obvious (either alone or in combination with other prior art), including without limitation, the claim(s) of the '122 patent allegedly rendered obvious, every combination of prior art references alleged to render each such claim obvious, any evidence that allegedly shows a motivation to combine the prior art references, and the education level and experience that a person of ordinary skill in the art of the claimed invention allegedly would possess.
- 15. The factual basis for any contention by Teva that the '122 patent is invalid due to a prior public use or on-sale bar, including without limitation a description of each instance or event that is alleged to constitute a prior public use or sale in the United States and the claim(s) of the '122 patent alleged to be invalid as a result.
- 16. The factual basis for any contention by Teva that the '122 patent is invalid due to a failure to satisfy the written description, enablement, and/or best mode requirements.
- 17. The factual basis for any contention by Teva that the '122 patent is invalid due to inventorship.
- 18. The factual basis for any contention by Teva that the '122 patent is invalid due to indefiniteness.
- 19. The factual basis for any contention by Teva that the '122 patent is unenforceable due to inequitable conduct, including without limitation, all information alleged to have been

misrepresented or withheld from the PTO, the person(s) who allegedly withheld or misrepresented such information, the factual basis for any contention that such information was material, and any evidence that shows or suggests that the alleged misrepresentation or omission was made with the intent to deceive the PTO.

- 20. Any document retention and destruction policy in effect at Teva U.S.A. and/or Teva Israel at any time since entry into the generic market for risedronate was first contemplated.
- 21. Efforts made by Teva U.S.A. and/or Teva Israel to collect documents for production to P&G in response to its Requests for Production of Documents and Things, including what locations and whose files were searched.
- 22. Documents and things concerning the foregoing topics.
- 23. Persons knowledgeable about the foregoing topics.